

DOCKET NO.: Z70606-2 US
PATENT APPLICATION

SERIAL NO.: 10/627,198
FILED: JULY 25, 2003

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claim 1 (original) A granule formulation comprising 11-[4-[2-(2-hydroxyethoxy)ethyl]-1-piperazinyl]dibenzo[b,f][1,4]thiazepine or a pharmaceutically acceptable salt thereof and a freely or very water-soluble binder, wherein the granules have a bulk density range of 0.15 g/cc to 0.60 g/cc and a tap density range of 0.20 g/cc to 0.70 g/cc and 80% of the granules are in the size range of 75 to 850 microns.

Claim 2 (original) A formulation according to claim 1 wherein 11-[4-[2-(2-hydroxyethoxy)ethyl]-1-piperazinyl]dibenzo[b,f][1,4]thiazepine is in the form of a fumarate salt.

Claim 3 (original) A formulation according to either claim 1 or claim 2 wherein the freely or very water-soluble binder comprises maltodextrin, mannitol, xylitol, pre-gelatinised starch, sucrose or poly[1-(2-oxo-1-pyrrolidinyl)ethylene].

Claim 4 (original) A formulation according to claim 3 wherein the binder is maltodextrin.

Claim 5 (original): A formulation according to claim 1 wherein the bulk density range is 0.26 g/cc to 0.400 g/cc and the tap density range is 0.342 g/cc to 0.500 g/cc.

Claim 6 (original): A formulation according to claim 1 which further comprises a sweetener.

Claim 7 (original) A granule formulation consisting of 11-[4-[2-(2-hydroxyethoxy)ethyl]-1-piperazinyl]dibenzo[b,f][1,4]thiazepine or a pharmaceutically acceptable salt thereof, a freely or very water-soluble binder, and a sweetener wherein the granules have a bulk density range of 0.15 g/cc to 0.60 g/cc and a tap density range of 0.20 g/cc to 0.70 g/cc and 80% of the granules are in the size range of 75 to 850 microns.

Claim 8 (original) A formulation according to claim 7 wherein 11-[4-[2-(2-hydroxyethoxy)ethyl]-1-piperazinyl]dibenzo[b,f][1,4]thiazepine is in the form of a fumarate salt.

Claim 9 (original): A formulation according to claim 1 wherein the moisture level in the granules is between 1.5 and 15%.

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Claim 10 (original) A formulation according to claim 9 wherein the moisture level in the granules is between 4 and 8%.

Claim 11 (original) A process for preparing a formulation as defined in claim 1 which process comprises:

- (i) fluidizing 11-[4,2-(2-hydroxyethoxy)ethyl-1-piperazinyl]dibenz[b,f][1,4]thiazepine or a pharmaceutically acceptable salt thereof and the freely or very water-soluble binder on a bed of air in a fluid bed;
- (ii) adding water to the fluid bed; and
- (iii) drying.

Claim 12 (currently amended) A method for treating ~~psychosis~~ psychoses which comprises administering an effective amount of a formulation as defined in claim 1 to a patient in need thereof.

Claim 13 (original) A kit comprising

- i) a granule formulation as defined in claim 1;
- ii) an aqueous medium;
- iii) optionally, instructions for use so that the granules can be dissolved or suspended in said aqueous medium for administration.

Claim 14 (original) A formulation according to claim 2 wherein the bulk density range is 0.26 g/cc to 0.400 g/cc and the tap density range is 0.342 g/cc to 0.500 g/cc.

Claim 15 (original) A formulation according to claim 3 wherein the bulk density range is 0.26 g/cc to 0.400 g/cc and the tap density range is 0.342 g/cc to 0.500 g/cc.

Claim 16 (original): A formulation according to claim 4 wherein the bulk density range is 0.26 g/cc to 0.400 g/cc and the tap density range is 0.342 g/cc to 0.500 g/cc.

Claim 17 (original): A formulation according to claim 2 which further comprises a sweetener.

Claim 18 (original): A formulation according to claim 3 which further comprises a sweetener.

Claim 19 (original): A formulation according to claim 4 which further comprises a sweetener.

Claim 20 (original): A formulation according to claim 5 which further comprises a sweetener.

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Claim 21 (original): A formulation according to claim 1 wherein the moisture level in the granules is between 1.5 and 15%.

Claim 22 (original): A formulation according to claim 2 wherein the moisture level in the granules is between 1.5 and 15%.

Claim 23 (original): A formulation according to claim 3 wherein the moisture level in the granules is between 1.5 and 15%.

Claim 24 (original): A formulation according to claim 4 wherein the moisture level in the granules is between 1.5 and 15%.

Claim 25 (original): A formulation according to claim 5 wherein the moisture level in the granules is between 1.5 and 15%.

Claim 26 (original): A formulation according to claim 6 wherein the moisture level in the granules is between 1.5 and 15%.

Claim 27 (original): A formulation according to claim 7 wherein the moisture level in the granules is between 1.5 and 15%.

Claim 28 (original): A formulation according to claim 8 wherein the moisture level in the granules is between 1.5 and 15%.

Claim 29 (original): A formulation according to claim 2 wherein the moisture level in the granules is between 4% and 5%.

Claim 30 (original): A formulation according to claim 3 wherein the moisture level in the granules is between 4 and 8%.

Claim 31 (original): A formulation according to claim 4 wherein the moisture level in the granules is between 4 and 8%.

Claim 32 (original): A formulation according to claim 5 wherein the moisture level in the granules is between 4 and 8%.

Claim 33 (original): A formulation according to claim 6 wherein the moisture level in the granules is between 4 and 8%.

Claim 34 (original): A formulation according to claim 7 wherein the moisture level in the granules is between 4 and 8%.

Claim 35 (original): A formulation according to claim 8 wherein the moisture level in the granules is between 4 and 8%.

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Claim 36 (original): The method as recited in claim 12 wherein the disease of the central nervous system is psychoses.

Claim 37 (original): The method as recited in claim 36 where the disease of the central nervous system is schizophrenia.

Claim 38 (original): The method according to claim 12 wherein the psychosis is schizophrenia.